

REMARKS

Applicant appreciates the time taken by the Examiner to review Applicant's present application. This application has been carefully reviewed in light of the Official Action mailed January 28, 2008. Applicant respectfully requests reconsideration and favorable action in this case.

Rejections under 35 U.S.C. § 102

Claims 23, 24, 26 and 27 stand rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,752,809 ("*Gorek*"). Additionally, Claims 23, 24, 26 and 27 stand rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,610,079 ("*Li*"). Applicant respectfully submits that neither *Gorek* nor *Li* anticipates Claim 23.

Claim 23 recites:

A method of introducing a fluid into a bone,
comprising:
 advancing a bone tap into the bone, the bone tap
 comprising a passage, one or more openings
 communicating with the passage, and threading located
 near an end of a body of the bone tap;
 introducing a fluid to the bone through at least one
 of the openings;
 allowing the fluid to spread to a portion of the bone;
 and
 introducing a bone fastener into an opening formed
 by the bone tap

In embodiments according to Claim 23, fluid is introduced into a bone through openings in a bone tap. A bone tap is a device that prepares an opening for insertion of a fastener. For example, a threaded section on a bone tap creates threads in an opening that are complementary to the threads of the bone screw that will be inserted in the opening. See ¶30. A bone fastener is then introduced into the opening formed by the bone tap.

In *Gorek*, on the other hand, an opening is tapped and then a threaded cannula screwed into the pre-tapped hole. Fluid is introduced through the cannula, not the bone tap that tapped the hole. See *Gorek*, col. 4, lines 1-4; col. 5, lines 47-50) (stating "the surgeon places the

cannula into the tapped hole" and "the outer surface of the cannula 100 is threaded with outer threads 114 for engagement with inner threads of a tapped drill hole . . ."). Thus, in *Gorek*, fluid is not introduced through the bone tap as recited in Claim 23.

According to *Li*, a fastener 70 can be installed with an installation tool. The fastener 70 can define a passage through which a needle 24 passes. Fastener 70 can be put in place to secure tissue together. Needle 24 is inserted into the bore of fastener 70 and polymer injected through needle 24 and through the fastener 70. In contrast to Claim 23, polymer is injected through a fastener of *Li*. Thus, in *Li*, fluid is not introduced through the bone tap as recited in Claim 23.

Claims 33-34, 36-38, 40, 42, and 44-47, 49 and 51-53 stand rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,622,731 ("Daniel").

Claim 33 recites:

A method of introducing a fluid into a bone, comprising:
advancing a bone tap into the bone, the bone tap comprising
a passage, one or more openings communicating with the passage,
and threading located near an end of a body of the bone tap;
introducing a fluid to the bone through at least one of the
openings;
allowing the fluid to spread to a portion of the bone; and
coupling a removable driver to the bone tap, and using the
driver to remove the bone tap from the bone.

Claim 33 includes advancing a bone tap into the bone and introducing fluid to the bone through at least one of openings in the bone tap. Claims 40 and 47 recite "advancing [a/the] bone tap to a first location in the bone" and "introducing fluid to the first bone location through one or more openings in the bone tap." As discussed above, a bone tap is a device that prepares an opening for insertion of a fastener. *See ¶30*. Consequently, according to Claims 33, 40 and 47, the device used to prepare an opening for insertion of a subsequent fastener, such as a bone screw, can also be used to introduce fluid into the bone.

Daniel, in contrast, teaches a system of delivering an electrode to a tumor to ablate the tumor. *See Daniel* col. 2, lines 1-6. An introducer is used to pass through bone to reach the tumor then an electrode is extended from the introducer for deployment into the tumor. *See*

Daniel col. 17, lines 59-col. 19, line 28. The electrode can include apertures through which conductive viscoelastic gel can be introduced to the tumor.

In contrast to the recitations of Claims 33, 40 and 47, the introducer of *Daniel* is not a bone tap as it is not used to prepare an opening for a fastener. The threaded section of the introducer can be self tapping to allow a surgeon to screw in the introducer through harder bone to reach a tumor but it is not used as a bone tap to tap an opening for a subsequent fastener. As a further distinction, the fluid of *Daniel* is not introduced through openings in the introducer, but is, instead, introduced through apertures in an electrode extending from the introducer. See FIGURES 18B and 19B of *Daniel*. As *Daniel* does not disclose a bone tap having openings through which fluid is introduced to the bone, *Daniel* does not anticipate Claims 33, 40 or 47.

Claim 33 further recites that a removable driver can be attached to the bone tap to remove the bone tap from the bone. Unlike the driver of Claim 33, handle 296 of *Daniel* does not appear to be removable. For example, FIGURE 21 of *Daniel* illustrates that a connection from a power source run through handle 296 indicating that handle 296 is not removed to access the introducer.

Claim 34, 42 and 49 recite that the fluid comprises "bone cement". It is known in the art that bone cement cures into a hard substance. The fluid of *Daniel* however is not bone cement. Instead, it is a viscoelastic conductive gel or paste that stays within the bone during ablation to uniformly deliver electromagnetic energy. The viscoelastic gel does not appear to harden as does cement. See United States Patent No. 4,299,231 (cited in *Daniel*), col. 2, lines 10-21, describing viscoelastic gels.

For the foregoing reasons, Applicant submits that *Gorek*, *Li* and *Daniel* do not anticipate Claims 23, 33, 40 or 47. Applicant respectfully submits that the additionally cited references do not make up for the deficiencies of *Gorek*, *Li* or *Daniel* either alone or in combination and therefore the cited references, alone or in combination, do not render Claims 23, 33, 40 and 47 obvious.

Conclusion

Applicant has now made an earnest attempt to place this case in condition for allowance. Other than as explicitly set forth above, this reply does not include an acquiescence to statements, assertions, assumptions, conclusions, or any combination thereof in the Office Action. For the foregoing reasons and for other reasons clearly apparent, Applicant respectfully requests full allowance of Claims 23, 33, 40 and 47 and their respective dependent Claims. The Examiner is invited to telephone the undersigned at the number listed below for prompt action in the event any issues remain.

Respectfully submitted,
Frankel, *et al.*



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